

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: U.S. Patent No. 5,061,703

Inventors: Joachim BORMANN, Markus GOLD, and Wolfgang SCHATTON

Assignee: Merz Pharma GmbH & Co. KGaA

Title: ADAMANTANE DERIVATIVES IN THE PREVENTION AND TREATMENT OF CEREBRAL ISCHEMIA

Issue Date: October 29, 1991

**SECOND SUPPLEMENT TO REQUEST
FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156**

Mail Stop Hatch-Waxman PTE
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This supplement relates to the pending request for extension of the term of U.S. Patent No. 5,061,703 ("the '703 patent") pursuant to 35 U.S.C. § 156, which was submitted on December 9, 2003 by Forest Laboratories, Inc. ("Forest") acting as agent of the patent owner Merz Pharma GmbH & Co. KGaA ("Merz"). The USPTO has stated that, subject to final review, the '703 patent "is considered eligible for patent term extension." See February 28, 2007 Letter from USPTO to FDA regarding NAMENDA™ (memantine hydrochloride).

A first supplement to the December 9, 2003 Request was filed on December 27, 2006 to indicate that the '703 patent had been reexamined by the USPTO, and to provide a copy of the Certificate of Reexamination that issued on November 7, 2006. As stated in the first supplement, the reexamination proceeding resulted in the amendment of claims 1 and 10, confirmation of the patentability of claims 2-9 and 11-13, and addition of claims 14-19.

Pursuant to 37 CFR 1.765, this supplement is submitted to indicate that claims 14-19, which were added during the reexamination proceeding, cover methods of using NAMENDA™ (memantine hydrochloride) for the treatment of moderate to severe dementia of the Alzheimer's type, for which NAMENDA™ has been approved. Thus, in addition to claims 1 and 10, other claims that cover the approved method for using the approved product include claims 2, 3, 6, 8, and 11-19.

The patent owner, Merz, hereby requests that the Commissioner grant an extension of 1250 days to U.S. Patent No. 5,061,703.

Favorable action is earnestly solicited.

Dated: November 13, 2008

Respectfully submitted,

By

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